

OCT -2 1996

K962626

510(k) SUMMARY

1. PERSONNEL AND DATE (807.92(a)(1))

1.1. Submitter

Kenad SG Medical Inc.
2692 Huntley
Memphis, TN 38132

1.2.. Contact Person

Kenneth Elmore
President and CEO
Kenad SG Medical Inc.

1.3.. Date Of summary Preparation

This summary was prepared in April and May 1996.

2. DEVICE NAME (807.92(a)(2))

As noted in the Cover Letter, five similar devices are grouped within this 510(k) notification. These devices differ only in minor design aspects. Their function, application and use is identical.

2.1. Trade Or Proprietary Name

Patient Protective Limb Holder (Universal) is the trade or proprietary name for the devices which are the subject of this Premarket Notification Submission. Within this name, there are five Kenad Limb Holders.

KENAD Catalog #	Description
50-1400	White Limb Holder
50-1500	Deluxe Blue Limb Holder
50-1500e	Economy White Limb Holder
50-1600	Black Limb Holder w/ Removable Cuff
50-1700	Pediatric Limb Holder

2.2. Common Or Usual Name

Protective Restraint 21CFR 880.6760

3. LEGALLY MARKETING DEVICE (807.92(a)(3))

The Kenad Limb Holders that are the subject of this Premarket Notification Submission are comparable to Patient Protective Limb Holder from Danek Medical, Inc. Danek successfully filed a premarket notification for Patient Protective Limb Holder at Document Control number K823815, January 17, 1983.

4. DEVICE DESCRIPTION (807.92(a)(4)) (p 11)

4.1. General Description

The Kenad Limb Holders subject to this Premarket Notification are depicted in the figure at ATTACHMENT 6. As depicted in this figure, Kenad Limb Holders are assemblies of the following modules: Ankle/Wrist Cuff, Ankle/Wrist Strap, Connector Strap, Quick Release Buckle and Bed Strap.

The Ankle/Wrist Cuff is a rectangular, two sided material. On the side which contacts skin, the cuff is made from blue or white polyurethane foam. At one end of the rectangle, a patch of Velcro hooks are stitched to the foam with 12 pound nylon thread. Heat bonded to the foam back is a piece of blue or white Velcro pile.

Except for Black Limb Holder with Removable Cuff (Catalog # 50-1600), the Ankle/Wrist Strap is affixed to the Ankle/Wrist Cuff by sewing using 12 pound nylon thread. For Black Limb Holder, a Velcro hook strip is sewn to one end of the Ankle/Wrist Strap. The Velcro hook strip then affixes to the Velcro pile of the cuff. Affixed by sewing to one end of the Ankle/Wrist Strap is a polished metal buckle for locking the Ankle/Wrist strap in place around the ankle/wrist.

The Connector Strap is affixed by sewing with 12 pound nylon thread to the Ankle/Wrist Strap. Affixed by sewing to the other end of the Connector Strap is the female or male end of the Quick Release Buckle.

The Bed Strap comes as either a loop able or threadable end for anchoring to a fixed object. Affixed by sewing to one end of the Connector Strap is the complementary female or male end of the Quick Release Buckle.

The material used to make the straps is woven polypropylene. The polypropylene color is either black or white, and its width is either a nominal 1 or 1.5 inch. The variations are outlined in more detail in the Table also included at ATTACHMENT 6.

4.2. How Limb Holders Function

The Ankle/Wrist Cuff is placed around the ankle/wrist, and held in place by Velcro. The cuff is then surrounded by the Ankle/Wrist Strap, and held in place by a buckle. The Bed Strap is affixed to an immovable object either by looping or threading, and the Bed Strap is connected to the Connector Strap via the Quick Release Buckle. Slack is removed from the Connector Strap so that the limb is comfortably held close to the bed.

5. INTENDED USE (807.92(a)(5))

5.1. Indications

Kenad Limb Holders are indicated for medical purposes where a patient's arm and leg movement must be limited to the extent necessary for treatment, examination or protection of the patient or others.

5.2. Patient Population

Kenad Limb Holders are used with adults and children.

5.3. Indications Different From Substantially Equivalent Device

The indications and patient population for the Kenad devices are identical to the legally marketed device cited above at Section 10.

6. COMPARISON TO LEGALLY MARKETING DEVICE (807.92(a)(6))

The Kenad Limb Holders that are the subject of this Premarket Notification Submission are comparable to Patient Protective Limb Holder from Danek Medical, Inc. A comparison of these devices was provided at Section 6 in the Premarket Notification Submission.

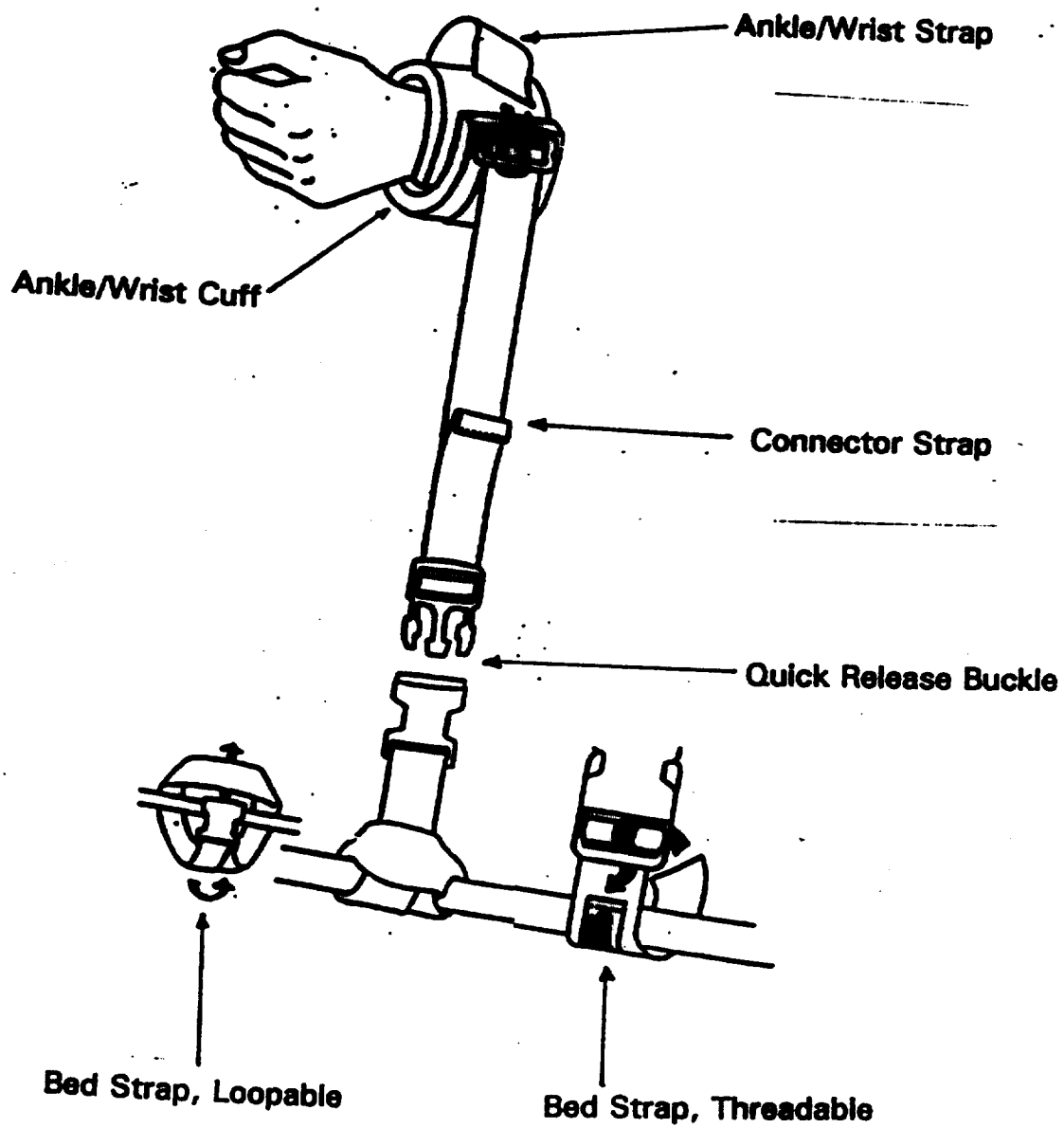
7. PERFORMANCE DATA (807.92(b))

More than 150,000 pairs of Kenad Limb Holders were sold over the last 5 years. Assuming 100% usage, there have been more than 300,000 contacts between ankles and/or wrists over the last 5 years. During this time, Kenad received no patient injury or product failure complaints.

8. SAFETY, EFFICACY AND PERFORMANCE CONCLUSION (807.92(b)(3))

The absence of patient injury or product failure complaints following more than 300,000 product uses over 5 years indicates these products are safe and effective.

ATTACHMENT 6



CATALOG #	50-1400 White Limb Holder	50-1500e Economy Limb Holder	50-1500 Deluxe Limb Holder	50-1700 Pediatric Limb Holder	50-1600 Detachable Cuff Limb Holder
CUFF					
Color	White	White	Blue	Blue	Blue
Dimensions (Nominal)	12 X 3	12 X 3	13 X 3	9 X 2	13 X 3
STRAP (Ankle/Wrist, Bed, Connector)					
Color	White	White	White	White	White
Width	1.5"	1"	1.5"	1"	1.5"
BED STRAP					
Attachment	Threadable	Loopable	Loopable	Loopable	Loopable
QUICK RELEASE					
Width	1.5"	1"	1.5"	1"	1.5"